(ii) *Indications for use.* Treatment of bacterial infections of the upper respiratory tract (tonsillitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E. coli, Proteus* spp., and *Pasteurella* spp., and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., and *E. coli,* when caused by susceptible organisms.

(iii) *Limitations.* Administer intramuscularly. If continued treatment is indicated, oral dosage is recommended. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment are recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37330, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

### § 522.90b Ampicillin trihydrate for sterile suspension.

(a) *Specifications.* When reconstituted, each milliliter contains ampicillin trihydrate equivalent to 50, 100, or 250 milligrams of ampicillin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.40 of this chapter.

(d) *Conditions of use.* (1) *Dogs*—(i) *Amount.* 3 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment against strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* Administer by subcutaneous or intramuscular injection. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 3 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment against strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* Administer by subcutaneous or intramuscular injection. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle*—(i) *Amount.* 2 to 5 milligrams per pound of body weight once daily by intramuscular injection.

(ii) *Indications for use.* Treatment of respiratory tract infections caused by organisms susceptible to ampicillin, bacterial pneumonia (shipping fever, calf pneumonia, and bovine pneumonia) caused by *Aerobacter* spp., *Klebsiella* spp., *Staphylococcus* spp., *Streptococcus* spp., *Pasteurella multocida,* and *Escherichia coli.*

(iii) *Limitations.* Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment and for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment and for 144 hours (6 days) after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993]

### § 522.90c Ampicillin sodium for aqueous injection.

(a) *Specifications.* When reconstituted, each milliliter contains ampicillin sodium equivalent to 300 milligrams of ampicillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use. Horses*—(1) *Amount:* 3 milligrams per pound of body weight twice daily.

(2) *Indications for use.* Treatment of respiratory tract infections (pneumonia and strangles) due to *Staphylococcus* spp., *Escherichia coli,* and *Proteus mirabilis,* and skin and soft tissue infections (abscesses and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli,* and *P. mirabilis,* when caused by susceptible organisms.

(3) *Limitations.* Administer either intravenously or intramuscularly. Treatment should be continued 48 hours after all symptoms have subsided. If no response is seen in 4 to 5 days, reevaluate diagnosis. Not for use in horses or other animals which are raised for food

production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

### § 522.144 Arsenamide sodium aqueous injection.

(a) *Chemical name.* [[(*p*-Carbamoylphenyl) arsylene]dithio diacetic acid, sodium salt.

(b) *Specifications.* The drug is a sterile aqueous solution and each milliliter contains 10.0 milligrams of arsenamide sodium.

(c) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) For the treatment and prevention of canine heartworm disease caused by *Dirofilaria immitis.*

(2) It is administered intravenously at 0.1 milliliter per pound of body weight (1.0 milliliter for every 10 pounds) twice a day for 2 days. For dogs in poor condition, particularly those with evidence of reduced liver function, a more conservative dosage schedule of 0.1 milliliter per pound of body weight daily for 15 days is recommended.

(3) Restricted to use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 43 FR 27785, June 27, 1978; 45 FR 56798, Aug. 26, 1980; 55 FR 26683, June 29, 1990]

### § 522.147 Atipamezole hydrochloride.

(a) *Specifications.* Each milliliter of sterile injectable solution contains 5.0 milligrams of atipamezole hydrochloride.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Inject intramuscularly the same volume as that of medetomidine used.

(2) *Indications for use.* To reverse clinical effects of the sedative and analgesic agent medetomidine hydrochloride.

(3) *Limitations.* For intramuscular use only. Not recommended for use in pregnant or lactating animals, or animals intended for breeding. Atipamezole has not been evaluated in breeding animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 48830, Sept. 17, 1996]

### § 522.150 Azaperone injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 40 milligrams of azaperone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* Control of aggressiveness when mixing or regrouping weanling or feeder pigs weighing up to 80 pounds.

(2) *Dosage.* 2.2 milligrams per kilogram (1 milligram per pound).

(3) *Limitations.* Inject by deep intramuscular injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 48229, Oct. 18, 1983, as amended at 62 FR 61625, Nov. 19, 1997]

### § 522.161 Betamethasone acetate and betamethasone disodium phosphate aqueous suspension.

(a) *Chemical names.* Betamethasone acetate: 9-α-Fluoro-16-β-methylprednisolone - 21 - acetate ($C_{24}H_{31}FO_6$). Betamethasone disodium phosphate: 9-α-Fluoro-16-β-methylprednisolone-21-disodium phosphate ($C_{22}H_{28}FNa_2O_8P$).

(b) *Specifications.* The drug is a sterile aqueous suspension and each cubic centimeter contains: 12 milligrams of betamethasone acetate (equivalent to 10.8 milligrams of betamethasone), 3.9 milligrams of betamethasone disodium phosphate (equivalent to 3 milligrams of betamethasone), 2 milligrams of dibasic sodium phosphate, 5 milligrams of sodium chloride, 0.1 milligram of disodium EDTA, 0.5 milligram of polysorbate 80, 9 milligrams of benzyl alcohol, 5 milligrams of sodium carboxymethylcellulose, 1.8 milligrams of methylparaben, 0.2 milligram of propylparaben, hydrochloric acid and/or sodium hydroxide to adjust pH, and water for injection q.s.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Conditions of use.* It is used or intended for use by intra-articular injection of horses for the treatment of various inflammatory joint conditions; for